

originally filed. Support for the subject matter of Claim 50 is found *inter alia*, on page 2, lines 23-33 to page 3, line °, and on page 18, lines 19-33 to page 19, lines ° to 2 in the application as originally filed.

1. Restriction/Election Requirement

In the Office Action mailed May 3, 2001, the Examiner required restriction/election of the subject matter of the claims as follows:

- Group I: claims 1-19, directed to a peptide agonist, and pharmaceutical compositions and kits comprising this agonist; and claims 30-31, directed to methods of treating a host comprising introducing CTLs specific for CEA and a peptide agonist;
- Group II: claims 20-29, directed to an isolated DNA, and vectors and host cells comprising this DNA;
- Group III: claims 32-36, directed to a method of inhibiting carcinoma cells in a patient comprising administering the peptide agonist of claim 1;
- Group IV: claims 32 and 37, directed to a method of inhibiting a carcinoma cells in a patient comprising administering the peptide agonist of claim 1 and a vector encoding CEA; and
- Group V: claim 38, directed to a method of inhibiting a carcinoma comprising adoptively transferring the CEA epitope or agonist peptide-specific CTLs alone or in combination with an agonist peptide of Group I;
- Group VI: claim 39, directed to a method of inhibiting carcinoma cells in a mammal comprising generating CEA epitope or agonist peptide-specific CTLs by administration of an agonist peptide.
- Group VII: claim 39, directed to a method of inhibiting a carcinoma comprising generating CEA epitope or agonist peptide-specific CTLs by administration of a vector encoding CEA;
- Group VIII: claim 39, directed to a method of inhibiting a carcinoma comprising generating CEA epitope or agonist peptide-specific CTLs by administration of agonist peptide-pulsed antigen presenting cells;
- Group IX: claims 40-41, directed to a peptide comprising an antagonist of SEQ ID NO:1, and a pharmaceutical composition comprising this antagonist;

- Group X: claims 42-43, directed to a method of inhibiting CEA-specific immune responses comprising administering a peptide comprising an antagonist of SEQ ID NO:1; and
- Group XI: claims 44-45, directed to a peptide pulsed cell comprising an antigen presenting cell pulsed with a peptide agonist of Group I (Office Action, pages 2-3).

The Examiner stated that the claims of Groups I-XI were not so linked as to form a single, general inventive concept under PCT Rule 13.1 (Office Action, page 2).

The Examiner also required election of the species of the subject matter of the claims as follows:

- Groups I-XI: a specific sequence, such as any one of SEQ ID NO:3-18;
- Group I: 1) a specific immunostimulatory molecule, as recited in claim 9; 2) a specific HLA Class I molecule, as disclosed on page 32 of the specification, or recited in claim 5; 3) a specific CEA epitope, as disclosed on page 11 of the specification; and 4) a specific tumor, as recited in claim 36;
- Group II: 1) a vector encoding a specific peptide, as recited in claim 5; and 2) a specific HLA Class I molecule, as disclosed on page 32 of the specification;
- Group III or V (sic): 1) a specific immunostimulatory molecule, as recited in claim 34; and 2) a specific carcinoma cell, as recited in claim 36;
- Group V: a specific carcinoma cell, as recited in claim 36; and
- Group XI: a specific antigen presenting cell, as recited in claim 45 (Office Action, page 4).

The Examiner stated that the species for Groups I-IX lacked unity of invention, because they were not so linked as to form a single inventive concept under PCT Rule 13.1 (Office Action, page 4).

2. Traversal: Election of Groups I-XI

Applicants respectfully traverse the restriction/election for the claims of Groups I-XI as set forth in the Office Action (see pages 2-3), and shown above. MPEP §1893.03(d) states:

Examiners are reminded that unity of invention (not restriction) practice is applicable in international applications (both Chapter I and Chapter II) and in national stage applications...The basic principle [of unity of invention] is that an application should relate to only one invention or, if there is more than one invention, that application would have the right to include in a single application only those inventions which are so linked as to form a single general inventive concept.

Applicants are therefore entitled to claims to one invention, or claims to more than one invention, where these inventions are linked by a general inventive concept. MPEP §1893.03(d) further states:

A group of inventions is considered linked to form a single general inventive concept where there is a technical relationship among the inventions that involve at least one common or corresponding special technical feature. The expression special technical feature is defined as meaning those technical features that define the contribution which each claimed invention, considered as a whole, makes over the prior art (emphasis added).

Accordingly, Applicants are entitled to claims to more than one invention, where there is at least one common special technical feature shared by the inventions, and this special technical feature defines the contribution of the inventions over the prior art.

It is respectfully asserted that the claims of the instant application share unity of invention. For example, Group I claims share a single general inventive concept (i.e., a special technical feature) with the claims of Groups III, Group IV, and Group VI as set forth in the

Office action (see pages 2-3). Groups I, III, IV, and VI are listed as follows:

- Group I: claims 1-19, directed to a peptide agonist, and pharmaceutical compositions and kits comprising this agonist; and claims 30-31, directed to a method of treating a host having a tumor comprising introducing CTLs specific for CEA and a peptide agonist;
- Group III: claims 32-36, directed to a method of inhibiting carcinoma cells in a patient comprising administering the peptide agonist of claim 1;
- Group IV: claims 32 and 37, directed to a method of inhibiting a carcinoma cells in a patient comprising administering the peptide agonist of claim 1 and a vector encoding CEA; and
- Group VI: claim 39, directed to a method of inhibiting carcinoma cells in a mammal comprising generating CEA epitope or agonist peptide-specific CTLs by administration of an agonist peptide.

Therefore, Group I claims are directed to a peptide agonist, and compositions, kits, and treatment methods employing the peptide agonist. Group III, IV, and VI claims are directed to various treatment methods employing the peptide agonist. Accordingly, the claims of Groups I, III, IV, and VI share the peptide agonist as the common special technical feature.

The Examiner states:

Groups I, III-VIII and X are unique methods. Groups I/III-VIII and X differ with respect to their endpoints. Groups I, and III-VIII have essentially the same endpoints, but differ with respect to their respective ingredients and/or process steps.

However, the proper inquiry for determining unity of invention is not to ask whether the claims of Group I, III, IV, and VI have different “ingredients”, etc., but whether they share a common special technical feature. Here, it is clear that the claims of Group I, III, IV, and VI share the peptide agonist as a common special technical feature.

In support of Applicants arguments, it is noted that corresponding International Application No. PCT/US98/197494 was found to have unity of invention. Applicants point to the page 1 of the attached copy of the International Search Report for the International Application. On page 1, the box for "Unity of invention is lacking" is not checked. This indicates that International Application No. PCT/US98/197494 was found to have unity of invention by the International Searching Authority.

Further, Applicants respectfully submit that the examination of the claims of Group I, III, IV and VI would not impose an undue burden on the Examiner. It is noted that a search for the subject matter of the claims of the invention has been performed by the International Searching Authority for corresponding International Application No. PCT/US98/197494 (see the International Search Report, attached hereto). Applicants therefore respectfully request reconsideration regarding the restriction/election requirement as set forth for the instant application.

3. Traversal: Election of Species

Applicants respectfully traverse the restriction/election requirement as set forth for the species described in the Office Action (see page 4), and shown above. MPEP §1893.03(d) states:

A group of inventions is considered linked to form a single general inventive concept where there is a technical relationship among the inventions that involve at least one common or corresponding special technical feature. The expression special technical feature is defined as meaning those technical features that define the contribution which each claimed invention, considered as a whole, makes over the prior art (emphasis added).

Accordingly, Applicants are not entitled to claims to more than one invention where these inventions have different special technical features that define different inventive contributions over the prior art.

The Examiner states:

The species are distinct from the other because the encompassed products [sic] each peptide, each nucleic acid, each immunostimulatory molecule, each class I molecule, and each carrier differ with respect to their physiological properties, and each of the tumors have different etiologies....(Office Acton, page 5).

However, the proper inquiry for determining unity of invention is not to ask whether the species of the claims have different “etiologies”, etc., but whether they have a different special technical features that define the contribution over the prior art. The Examiner has failed to explain how the various species would comprise different inventive contributions over the art. Yet, in accordance with MPEP §1893.03(d), the Examiner is required to “specifically describ[e] the unique special technical feature in each group”, i.e., the distinct inventive contribution over the prior art.

Applicants respectfully assert that the species of the claims of the instant application share unity of invention. In support of this, it is noted that corresponding International Application No. PCT/US98/197494 was found to have unity of invention (see the International Search Report, attached hereto). Further, Applicants respectfully submit that the examination of claims directed to the aforementioned species would not impose an undue burden on the Examiner. Regarding the nucleotide/amino acid sequences of the application, Applicants note that “[i]t has been determined [by the Commissioner] that normally ten sequences constitutes a

reasonable number for examination purposes” (see MPEP §803.04). Moreover, a search for the subject matter of the claims of the invention has been performed by the International Searching Authority for corresponding International Application No. PCT/US98/197494 (see the International Search Report, attached hereto). Applicants therefore respectfully request reconsideration of the restriction/election requirement as set forth for the instant application.

4. Election of Group I and Corresponding Species

The Examiner has required that Applicants to elect one of Group I-XI and the corresponding species for the elected group. The Examiner has stated that Applicants will be considered non-responsive unless their response is accompanied by an election (Office Action, page 4). Although Applicants traverse the restriction/election requirement for reasons described above, Applicants have elected elect Group I claims and the corresponding species:

- GM-CSF, as a specific immunostimulatory molecule;
- HLA-A2, as a specific HLA Class I molecule;
- YLSGANLNL (SEQ ID NO:1), as a specific CEA epitope;
- colorectal tumor, as a specific tumor; and
- YLSGADLNL (SEQ ID NO:2), as a specific agonist peptide.

In addition, Applicants have added Claims 46-50, which are directed to the elected subject matter of the invention. Support for the subject matter of the newly added claims is found in the application as originally filed (see above). It is believed that Applicants are fully responsive to the restriction/election requirement as set forth in the Office Action.

CONCLUSION

An action passing this case to issue is courteously urged. In the event that the Examiner is of the opinion that further discussion of the application would be helpful, the Examiner is hereby respectfully requested to telephone Applicants' undersigned representative at (212) 415-8742 and is assured of full cooperation in an effort to advance the prosecution of the instant application and claims to allowance.

AUTHORIZATION

The Commissioner is hereby authorized to charge any additional fees which may be required for the timely consideration of this amendment under 37 C.F.R. §§ 1.16 and 1.17, or credit any overpayment to Deposit Account No. 13-4500., Order No. 2026-4266US1. A DUPLICATE COPY OF THIS SHEET IS ATTACHED.

Respectfully submitted,
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